**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF VIRGINIA**
**ALEXANDRIA DIVISION**

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| GILDA HAGAN-BROWN,<br><br>Plaintiff,<br><br>v.<br><br>ELI LILLY AND COMPANY, an Indiana corporation,<br><br>Defendant. | Case No. 1:14-cv-01614-AJT-JFA<br><br>Hon. Anthony J. Trenga<br>Hon. John F. Anderson<br><br>**PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTIONS FOR JUDGMENT ON THE PLEADINGS** |
| JANINE ALI,<br><br>Plaintiff,<br><br>v.<br><br>ELI LILLY AND COMPANY, an Indiana corporation,<br><br>Defendant. | Case No. 1:14-cv-01615-AJT-JFA<br><br>Hon. Anthony J. Trenga<br>Hon. John F. Anderson<br><br>**PLAINTIFFS' RESPONSE TO DEFENDANT'S MOTIONS FOR JUDGMENT ON THE PLEADINGS** |

## PRELIMINARY STATEMENT

Defendant Eli Lilly and Company ("Lilly") moves for Judgment on the Pleadings in both of these cases, arguing that Plaintiffs' design defect claims are preempted. While Plaintiffs do not fully agree with Lilly's draconian view of preemption law, these stand-alone design defect claims are not central to Plaintiffs' cases. With the Court's permission, Plaintiffs' withdraw their stand-alone design defect claims.

There is, however, an important issue that needs to be addressed by the Court. This motion for judgment on the pleadings was filed in response to a Fed. R. Civ. P. 30(b)(6) deposition notice on the topic of the development and creation of the Cymbalta capsule and dosing levels.

Lilly argues that a Rule 30(b)(6) deposition on this topic *only* applies to a design defect claim and, since Lilly believes such claims are preempted, Plaintiffs are not permitted to conduct any discovery on this issue.

This argument, however, assumes a false premise—that discovery about the development and creation of the Cymbalta capsule and dosing levels is *exclusively* relevant to a design defect claim. It is not. What Lilly knew about its pill, its design, and its defects, goes directly to a failure-to-warn claim—the cause of action that is at the heart of the Complaints.

The issue of the Rule 30(b)(6) deposition was left pending by the Magistrate Judge, who ruled that, if the Court grants Lilly's motion for judgment on the pleadings, there will be no deposition. Otherwise, if the Court has not ruled on Lilly's motion by May 7, 2015, Lilly must produce a witness. In discussing the matter before the Magistrate Judge, Plaintiffs' counsel argued that the disposition of this motion had no bearing on the permissibility of the Rule 30(b)(6) motion because it was relevant to Plaintiff's other "non-design-defect" claims. Plaintiffs' counsel asked if Plaintiffs could seek the Court's guidance on this issue as part of this motion, and the Magistrate Judge indicated he would welcome this Court's guidance. Thus, although Plaintiffs withdraw their design defect claims, Plaintiffs request guidance on whether Plaintiffs should be permitted to take a Rule 30(b)(6) deposition regarding the development and creation of the Cymbalta capsule and dosing levels as part of their remaining claims.

## **BACKGROUND**

On March 23, 2015, Plaintiffs served a deposition notice pursuant to Fed. R. Civ. P. 30(b)(6), designating four topics: (1) Cymbalta clinical trials, (2) the development and creation of the European Cymbalta label, (3) Lilly's marketing relationship with WebMD, and (4) the development and creation of the Cymbalta capsule and dosing levels. The fourth topic, which

prompted this motion, states:

> **The Cymbalta Capsule**
>
> 1. The design and dosing of the Cymbalta capsule. For clarity, the witness should be able to testify with regard to the following:
>
>    a. Why was a 20 mg dose of Cymbalta created[?] Who was responsible for making decisions about the available dosing levels for Cymbalta[?]
>
>    b. Why is the Cymbalta capsule in an enteric coating[?] Why was Cymbalta designed in a capsule form? How do the pellets within the Cymbalta capsule work in the absorption of the drug[?]
>
>    c. Why does the Cymbalta label advise against opening the Cymbalta capsule? What safety / efficacy concerns are associated with ingestion of Cymbalta outside of the capsule?
>
>    d. Were smaller doses, i.e., 10 or 5 mg ever considered? If so, why were they never created?

Lilly objected to this deposition notice, arguing that any testimony about the design of the Cymbalta pill and its dosing went exclusively to Plaintiffs' design defect claims, which, according to Lilly, is preempted. In response, Plaintiffs stated that withholding discovery on an issue because of an affirmative defense is improper, and that Plaintiffs would be filing a motion to compel on April 10, 2015.

The morning of April 10, 2015, in anticipation of Plaintiffs' motion to compel, Lilly filed this motion for judgment on the pleadings—laying the groundwork for its anticipated opposition to Plaintiffs' motion to compel. Later that afternoon, Plaintiffs filed their motion to compel. A copy of that motion is attached as Exhibit A.[1]

The motion to compel came on for hearing on April 17, 2015, wherein Lilly asserted that a deposition on the issue of Cymbalta's design and dosing was not warranted because Lilly had filed a potentially dispositive motion on Plaintiffs' design defect claim. Plaintiffs, however,

[1] Due to the size and number of exhibits, Plaintiffs have not also attached the Exhibits. The Exhibits, however, are available on both the Hagan-Brown and Ali EM/ECF dockets.

argued that it did not matter what this Court ruled on this design-defect issue because the relevance of a Rule 30(b)(6) deposition on the design and dosing of Cymbalta applied to both a design defect claim and failure-to-warn claims. The latter Lilly does not dispute is valid.

The Magistrate Judge ruled, however, that if this Court granted Lilly's motion for judgment on the pleadings, the deposition would not go forward, otherwise it would need to occur no later than May 7, 2015. Plaintiffs then stated that they were considering withdrawing the design-defect claims and, if so, still felt entitled to take the Rule 30(b)(6) deposition to learn about what Lilly knew was wrong with the drug (but failed to warn patients and doctors about). The Magistrate Judge explained that he could not rule on such a scenario because that was not before him. Plaintiffs' counsel asked if Plaintiffs could raise this issue with this Court so as to obtain clarification and the Magistrate Judge stated he would not have a problem with the Court reviewing this issue and offering its guidance.

## ARGUMENT

### I. WHEN THE DESIGN OF A DRUG COMPLICATES A KNOWN RISK, IT CREATES A FAILURE-TO-WARN CLAIM THAT IS NOT PREEMPTED

Unlike the question of whether a drug company has the power to redesign a drug's formulation without regulatory action, unilateral modification of its product label to include necessary information about its risks remains a duty under federal law:

> It has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.

*Wyeth v. Levine*, 555 U.S. 555, 570-71(2009). [2] *Levine* also makes clear that the design issues

[2] The Court supported its conclusion with the relevant FDA regulations. *See, e.g.*, 21 C.F.R. § 201.80(e) (requiring a manufacturer to revise its label 'to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug'); 21 C.F.R. § 314.80(b)

here, which deal with warnings or precautions that advise patients and their physicians of possible problems they may encounter from the drug are at the heart of the FDA's Changes Being Effected ("CBE") regulations, which allow drug companies to act on their own to add additional warnings or precautions:

> Among other things, th[e] changes being effected (CBE) regulation provides that if a manufacturer is changing a label to add or strengthen a contraindication, warning, precaution, or adverse reaction or to add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product, it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval.

*Id.* at 568 (internal quotations omitted). In *Levine*, the plaintiff was forced to have her arm amputated when a physician's assistant injected her with the antinausea drug Phenergan. *Id.* at 559. The plaintiff sued Wyeth, the manufacturer of the drug, for negligence and failure-to-warn product liability, arguing that the way the drug was administered could lead to serious side effects, i.e., the product's design was faulty. *Id.* On appeal, the Supreme Court refused to find the claims were preempted because nothing prevented Wyeth from *warning* about this design defect in its labeling. *Id.* at 578-79.

Similarly, in this case, nothing prevented Lilly from changing the warning label for Cymbalta to warn patients about the frequency, severity, and duration of the risks of withdrawal *or* to warn that the Cymbalta pill's design prevented any safe tapering below a 20 mg dose. In other words, provided Plaintiffs allege a claim that Cymbalta was not properly labeled, under *Levine*, the cause of action is not preempted.

## II. UNDER VIRGINIA LAW, A MANUFACTURER CAN CURE A DESIGN DEFECT BY PROVIDING PROPER WARNINGS

A design defect claim is fundamentally related to a failure-to-warn claim. The primary

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(placing responsibility for postmarketing surveillance on the manufacturer).

case on which Lilly relies, *Mutual Pharmaceutical Co., Inc. v. Bartlett,* 136 S.Ct. 2466 (2013), illustrates this principle. In *Bartlett,* a generic drug manufacturer was sued on a theory of defective drug design. *Id.* at 2472. The Supreme Court recognized that the underlying state product liability law (New Hampshire), which like Virginia is based on the Second Restatement of Torts,[3] gave a drug manufacturer two alternatives to keep an allegedly mis-designed drug from being defective: It could physically redesign the drug so that the risk was removed or it could strengthen the label warning to ameliorate the problems raised by the design. *Id.* at 2475. However, with regard to drugs, the Supreme Court explained that a generic manufacturer was forbidden from redesigning a drug under federal law. *Id.* Thus,

> Given the impossibility of redesigning sulindac, the only way for Mutual to ameliorate the drug's "risk-utility" profile—and thus to escape liability—was to strengthen "the presence and efficacy of [sulindac's] warning" in such a way that the warning "avoid[ed] an unreasonable risk of harm from hidden dangers or from foreseeable uses." [Citation omitted]. *See also Chellman,* 138 N.H., at 78, 637 A.2d, at 150 ("The duty to warn is part of the general duty to design, manufacture and sell products that are reasonably safe for their foreseeable uses. If the design of a product makes a warning necessary to avoid an unreasonable risk of harm from a foreseeable use, the lack of warning or an ineffective warning causes the product to be defective and unreasonably dangerous" (citation omitted)). ***Thus, New Hampshire's design-defect cause of action imposed a duty on Mutual to strengthen sulindac's warnings.***

*Id.* at 2475 (emphasis added). For purposes of a poorly designed drug, the primary ways to cure that design defect is to properly warn of the risks created by that design.[4]

In Virginia, the law follows the same logic. *See Morgen Industries, Inc. v. Vaughan,* 252 Va. 60, 66 (1996) ("A product is unreasonably dangerous if it is defective in assembly or

[3] *Compare Bartlett*, 133 S. Ct. at 2473 (2013) ("New Hampshire has adopted the doctrine of strict liability in tort as set forth in Section 402A of the Restatement (Second) of Torts.") *with Steingaszner v. Paramount Termite Control Co.*, 5 Va. Cir. 309 (1985) (discussing how Virginia Supreme Court has adopted Section 402A of the Restatement (Second) of Torts.").

[4] And in *Bartlett*, because *generic* drug manufacturers could not make changes to a drug label—as opposed to brand name manufacturers—a design defect claim against the *generic* manufacturer was preempted by federal law.

manufacture, unreasonably dangerous in design, or unaccompanied by adequate warnings concerning its hazardous properties").[5] A failure-to-warn claim and design defect are both predicated on the product being unreasonably dangerous as sold. Either the drug needs to be re-formulated to remove the defect (curing the defect) or the defect needs to be disclosed in the warnings (putting the user on notice of the defect). In either case, what the manufacturer knew about the design and function of the product are relevant—indeed they are a central element of the claims. *Funkhouser v. Ford Motor Co.*, 285 Va. 272, 281 (2013) (Plaintiff must show that a "manufacturer knows or has reason to know of the danger in a duty to warn case[.]").

## III. THERE WAS NO WARNING OF THE DANGERS CAUSED BY LILLY'S DESIGN OF CYMBALTA

The relevant facts are quite simple. Lilly knew that Cymbalta had a very high risk of causing withdrawal effects when patients stop taking it. *See* Complaint at ¶ 21. Studies show that at least 45% of patients who stop taking Cymbalta encounter withdrawal symptoms. *Id.* Yet, Lilly states in the U.S. label that "the following symptoms occurred at least 1% or greater" in patients stopping Cymbalta.[6] As a result, neither U.S. patients nor U.S. physicians were told

[5] *Morgen* is a more recent statement of long-established Virginia failure-to-warn product liability law, that was established in *Featherall v. Firestone Tire & Rubber Co.*, 219 Va. 949, 962 (1979). "In *Featherall*, we adopted the test set forth in the *Restatement (Second) of Torts* when we stated: The manufacturer of a chattel will be subject to liability when he (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous." *Owens-Corning Fiberglas Corp. v. Watson*, 243 Va. 128, 134 (1992).

[6] This label is in stark contrast to the Cymbalta label in Europe. *See* Summary of Product Characteristics, European Medicine Agency, at 6, *available at* http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/ human/000572/WC500036781.pdf. The European label states that "[i]n clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta[.]" *Id.* There is no "greater than or equal to" malarkey. The European label warns that withdrawal symptoms

about the 45 % overall risk of one or more of the symptoms happening if they quit Cymbalta. Plaintiffs will present evidence that both doctors and patients need the cumulative measure of risk, which answers the question they are most interested in – "If I stop taking the drug, what are the chances that I will suffer *any* withdrawal symptoms?" That question was not answered for Americans; because the 45% did not appear in the US label.[7]

Beyond that failure to warn lies a related failure to warn, which is the subject of this response. Lilly also knew that tapering (gradually taking less and less of the drug to allow the neural synapses to reprogram themselves to the absence of Cymbalta) was allegedly necessary to try to avoid withdrawal. Complaint at ¶¶ 17-18. And, as alleged in the Complaint, Lilly was selling a drug whose label told people to taper to discontinue, when the design of the drug did not allow for effective tapering. *Id.* at ¶¶ 19, 24-25. According to these alleged facts, Lilly should have warned patients and doctors that, in stopping Cymbalta, there was no way to possibly taper below the lowest available dose, i.e. 20 mg, and that patients still frequently suffered from withdrawal at that dose. Thus, while Plaintiffs allege a defect in Cymbalta's design, the cause of action contemplates a failure to warn about a known risk.

*Levine* holds that Lilly had the power and the duty to make changes to the label addressing this warning defect.[8] Lilly should have added a warning about the "20 mg cliff" to the Cymablta label. As a result, how much Lilly knew, when it knew it, what discussions it had

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"may be prolonged (2-3 months or more)." *Id.* Nowhere in the U.S. label is there a warning about duration. Finally, the European label provides instructions on how to taper, stating that Cymbalta "should be gradually tapered when discontinuing treatment over a period of no less than 2 weeks." *Id.* Again, the U.S. label makes no mention of how long Cymbalta should be tapered, and only provides that, if "intolerable symptoms occur . . . resuming the previously prescribed dose may be considered."

[7] In addition, the Complaints spell out the fact that Lilly's own clinical trial data showed that 9.6 to 17.2 % of the reactions were "severe." Complaint at ¶22.

[8] As discussed in Plaintiffs' Motion to Compel, Lilly was made aware of this labeling defect during its post-approval marketing of Cymbalta. *See* Motion to Compel at 14-15.

about changing the design, and the outcome of those discussions are directly relevant to the issue of Lilly's failure to add this new information to the label.[9]

**REQUEST FOR GUIDANCE**

While Plaintiffs are willing to withdraw their design defect counts, they need the Court's guidance on whether Plaintiffs should file an amended Complaint to include the design-related facts more explicitly in the failure to warn Counts. All of these facts are alleged in the original Complaints. Complaint ¶¶ 19, 20, 24, 29, 44-52. Because there was a separate defective design Count, they were not included in the specific pleading of the other Counts, but the factual allegations were incorporated by reference for each cause of action. *Id.* ¶¶ 37, 44, 53, 70, 79, 93. If the Court thinks it necessary, Plaintiffs respectfully request permission to amend their Complaints to remove the design defect claim and include the factual allegations in the other causes of action. *See People for Ethical Treatment of Animals v. Doughney*, 263 F.3d 359, 367 (4th Cir. 2001) ("The Federal Rules 'allow liberal amendment of pleadings throughout the progress of a case.'") (quoting *Elmore v. Corcoran,* 913 F.2d 170, 172 (4th Cir.1990)). It is relatively early in the case and the proposed amendment is made solely to apply previously-alleged facts to the other legal theories in the case.

Additionally, Plaintiffs request guidance on whether Plaintiffs should be permitted to take a Rule 30(b)(6) deposition on the development and creation of the Cymbalta capsule and dosing levels. This issue is, in truth, at the crux of this dispute. Discovery is set to complete on May 15, 2015. Waiting for this Court's ruling and then filing another motion to compel on these issues will needlessly delay resolution of this issue. Plaintiffs believe this proposed Rule 30(b)(6)

[9] Similarly, the causal relevance of the missing information is clear at this stage of the litigation. Plaintiffs will testify at trial that adding the fact that tapering to avoid withdrawal effects was difficult or impossible with the available Cymbalta capsules would have led to their not taking the drug, especially if combined with the disclosure of the 45% risk of withdrawal.

deposition is warranted, not for the purpose of asserting a design-defect claim, but for asserting a failure to warn claim.

## CONCLUSION

Although the separate counts for defective design will now be withdrawn, the design issues remain in the case, as they are part of the label's defects. As a result, Plaintiffs respectfully request that the Court enter its order:

1. Informing Plaintiffs whether the Court would like amended complaints filed; and

2. Informing the Parties whether Plaintiffs' Rule 30(b)(6) deposition on the development and creation of the Cymbalta capsule and dosing levels is permissible in the absence of a standalone design-defect cause of action because it applies to Plaintiffs' failure-to-warn claims.

DATED: April 21, 2015

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 21st day of April, 2015, a true copy of the foregoing PLAINTIFFS'RESPONSE TO DEFENDANT'S MOTIONS FOR JUDGMENT ON THE PLEADINGS was filed electronically with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

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